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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,131	01/31/2001	Toshihiko Yamauchi	TOYAM69.001A	8649

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 06/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/762,131	YAMAUCHI ET AL
	Examiner	Art Unit
	GAMBEL	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on 4/16/01

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) 4 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) 3-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☑ The drawing(s) filed on 1/31/01 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☑ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☑ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group IV (claims 3-5) in Paper No. 5 is acknowledged.

Claims 1- 2 (and 3 and 5 as they read on the non-elected inventions) have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Claims 3-5 are under consideration in the instant application.

Applicant should amend the claims to recite the elected invention of treating ITP with anti-gp39 antibodies as the "substance" in the claimed methods.

2. It is noted that JP 9-502186 and JP9-502184 have not been considered given that they are in Japanese and no translation nor an explanation of its contents have been provided. The information disclosure statement fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

4. Formal drawings, filed 1/31/01, comply with 37 CFR 1.84.

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 5 is rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed:

"wherein the administration of the substance is initiated when the candidate's immune response to platelet begins".

Applicant's amendment, filed 4/16/02 (Paper No. 3), asserts that no new matter has been added but does not provide sufficient direction for the written description for the above-mentioned "limitation".

The specification as filed does not provide sufficient written description or set forth the metes and bounds of this phrase. The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitation" as currently recited. For example, it is not clear at which stage of the disease or treatment of ITP and/or patient is being targeted by the claimed method. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

8. Claim 5 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite in the recitation "wherein the administration of the substance is initiated when the candidate's immune response to platelet begins" because ITP is a chronic disease. So it is not clear what times or stages of the disease / patient populations are encompassed by the claims methods. For example, it appears from the specification as filed that the claims may encompass treating ITP during remission (e.g. pages 2-3, overlapping paragraph, page 8, paragraph however it is not clear that the claimed "limitation" encompass this stage of disease.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 3-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kalled et al. (WO 98/39026; 1449, #10) (see entire document).

Kalled et al. teach methods of treating ITP (see page 2, paragraph 3; Claim 11) with anti-CD40L antibodies (see pages 6-8, Compounds and Claims). Given the teachings of administering therapeutically effective amounts of anti-CD40L antibodies on pages 9-11 in Dosages and Frequency of Treatment, it would have been inherent in treating ITP patients with anti-CD40L antibodies to prevent the onset of ITP and when the candidate's immune response to platelet begins in that such ITP patients would have been treated during remissions or in combination with standard therapies at the time the invention was made.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat ITP with anti-CD40L antibodies.

12. Claims 3-5 are rejected under 35 U.S.C. § 102(e) as being anticipated by Black et al. (U.S. Patent No. 6,001,358) (see entire document).

Black et al. teach methods of treating ITP (see column 14, line 40: column 32, line 5, lines 57-58) with anti-gp39 antibodies (see entire document). Given the teachings of administering therapeutically effective amounts of anti-gp39 antibodies in amounts to produce a therapeutic effect that can be determined by standard techniques well known to those ordinary skill in the art (e.g. column 33, paragraph 2) for therapeutic or prophylactic immunosuppression (e.g. column 34, paragraph 2-4), including inducing immunosuppression in the treatment and the prevention of diseases (e.g. column 33-34, overlapping paragraph); it would have been inherent in treating ITP patients with anti-CD40L antibodies to prevent the onset of ITP and when the candidate's immune response to platelet begins in that such ITP patients would have been treated during remissions or in combination with standard therapies at the time the invention was made.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat ITP with anti-gp39 antibodies.

13. Claims 3-5 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lederman et al. (U.S. Patent No. 5,993,816) (see entire document).

Lederman et al. teach methods of treating ITP (see column 11, line 33) with 5C8-specific (gp39-specific) antibodies (see entire document, including column 10, line 60 to column 11, line 35). Given the teachings of administering effective amounts of anti-5C8 antibodies to inhibit T cell activation of B cells; it would have been inherent in treating ITP patients with anti-CD40L antibodies to prevent the onset of ITP and when the candidate's immune response to platelet begins in that such ITP patients would have been treated during remissions or in combination with standard therapies at the time the invention was made.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat ITP with anti-5C8 antibodies.

14. Claims 3-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kalled et al. (WO 98/39026) AND/OR Black et al. (U.S. Patent No. 6,001,358) AND/OR Lederman et al. (U.S. Patent No. 5,993,816)
in view of either one of
Nemoto et al. (Br. J. Haematol. 91: 691-696, 1995) OR
Medical Letter on Drugs and Therapeutics 39: 6-8, 1996 OR
Williams et al. (Br. J. Haematol. 101: 779 - 782, 1998).

Kalled et al.(see entire document, including page 2, paragraph 3; Claim 11), Black et al. (see entire document, including column 14, line 40: column 32, line 5, lines 57-58) And Lederman et al. (see entire document, including column 11, line 33) are all taught above and teach treating and/or preventing ITP patients with anti-CD40L antibodies.

Given the ambiguity of the limitation recited in claim 5 "wherein the administration of the substance is initiated when the candidate's immune response to platelet begins", the additional references of Nemoto et al., Medical Letter on Drugs and Therapeutics and Williams et al. are provide to address different aspects of treating ITP and , in turn, the treatment of ITP with anti-CD40L antibodies.

Nemoto et al. teach the use of an immunosuppressant to the prevent the development of thrombocytopenia and suppress the increase in circulating antibodies against platelets in an experimental model of ITP (see entire document). Nemoto et al. Teach that corticosteroids are generally applied as the first-line drug therapy for ITP and that an immunosuppressant in combination with steroids would suppress the production of antibodies and phagocytic function in treating ITP patients (see page 695, column 2, paragraph 1).

Given the immunosuppressive properties of anti-CD40L antibodies, one of ordinary skill in the art at the time the invention was made would have been motivated to provide anti-CD40L antibodies in combination with known treatments of ITP in order to inhibit and prevent immune responses to platelets in ITP patients.

Medical Letter on Drugs and Therapeutics teach Rho(D) Immune globulin as well as prednisone or IVIG and sometimes splenectomy for the treatment of both acute and chronic ITP (see pages 6-8). Platelet counts increase after treatment and maintenance treatments would be helpful. (See page 7).

Williams et al. teach FcγRIIIa polymorphisms are implicated in the pathophysiology of ITP and be responsible for modulating the immune response in this heterogenous autoimmune disease (see entire document, including Abstract and Discussion). Williams teach that platelet antigens are targeted in this disease and that the destruction of antibody sensitized platelets are involved in this disease (see Introduction).

Given the immunosuppressive properties of anti-CD40L antibodies and the use of anti-CD40L antibodies in the treatment and prevention of ITP, as taught by Kalled et al., Black et al. and Lederman et al.; one of ordinary skill in the art at the time the invention was made would have been motivated to provide said anti-CD40L antibodies to treat ITP in combination with other known treatments of ITP in order to inhibit and prevent immune responses to platelets in ITP patients, given the role of anti-platelet antibodies play in ITP. One of ordinary skill in the art would have been motivated to provide anti-CD40L antibodies in both acute and chronic ITP to prevent and control the disease manifestations of this disease, including the anti-platelet responses and the consequences of anti-platelet responses. In addition, in certain instances of the expression of certain FcγRIIIa polymorphisms, as taught by Williams (also see Discussion); one of ordinary skill in the art at the time the invention was made would have been motivated to provide anti-CD40L antibodies in certain targeted patient populations to protect against more severe disease.

One of ordinary skill in the art at the time the invention was made would have been motivated to select anti-CD40L antibodies alone or in combination with other known and practiced treatments to prevent and to treat the elaboration and consequences of anti-platelet responses in ITP patients. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
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June 27, 2002